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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/721,118	11/25/2003	Cheng Shine Hwang	00216-654001 / H-254 (Ka)	6141
26161 7590 09/16/2008 FISH & RICHARDSON PC P.O. BOX 1022 MINNEAPOLIS, MN 55440-1022			EXAMINER YU, GINA C	
			ART UNIT 1617	PAPER NUMBER
			NOTIFICATION DATE 09/16/2008	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATDOCTC@fr.com

Office Action Summary

Application No.

10/721,118

Applicant(s)

HWANG ET AL.

Examiner

GINA C. YU

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 April 2008.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 2 and 4-46 is/are pending in the application.
4a) Of the above claim(s) 5-7, 9-28 and 46 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1, 2, 4, 8, 29-45 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SI-108)
Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

DETAILED ACTION

Receipt is acknowledged of amendment filed on April 7, 2008. The rejection made under 35 U.S.C. § 103(a) as indicated in the previous Office action dated November 30, 2007 is maintained for the reasons of record.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 2, 4, 8, and 29-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Billoni et al. (Aeta Derm. Venereol. 2000, 80:329-334) in view of Monneret et al. (J. of Immunol., 2002, 168:3563-3569).

Billoni teaches expression of peroxisome proliferators-activated receptors (PPARs) in human hair follicles. The reference teaches that 15-deoxy- $\Delta^{12,14}$ – prostaglandin J2 (15d-J2) is a potent adipogenesis inducer and PPAR- γ activator. The reference indicates that high clofibrate concentration (10^{-6} M) led to cessation of hair follicle growth in vitro. See p. 333. The reference goes on to teach that an unbalanced lipid metabolism can lead to an alteration of the human hair cycle, and suggests that that this alteration is at least partially due to altered PPAR-controlled pathways.

Billoni suggests that ligands other than clofibrate, that are specific for PPAR - δ and - γ expressed in the human hair follicles would confirm similar results. See Discussion.

The reference does not specifically mention 15-deoxy- $\Delta^{12,14}$ -PGD² (15d-PGD2).

Monneret teaches that PGD2 is a precursor to 15d-J2 and 15d-PGD2 is an analog of PGD2.

It would have been obvious to one of ordinary skill in the art at the time of the present invention to modify the teachings of Billoni by using 15-deoxy- $\Delta^{12,14}$ -PGD² to alter hair follicle growth in vivo because 1) Billoni teaches that a high concentration of PPAR-alpha leads to cessation of hair follicle growth in vitro, and suggest that ligands specific for PPAR- δ and - γ would yield a similar results; 2) the reference also teaches that 15d-J2 is a PPAR- γ activator; and 3) Monneret teaches that PGD2 is an analog of PGD2, which is a precursor to 15d-J2. Thus the skilled artisan would have expected that 15d-PGD2, the analog of its precursor would stimulate 15d-J2 and trigger the alteration of human hair growth.

Response to Arguments

Applicant's arguments filed on April 7, 2008 have been fully considered but they are not persuasive.

Applicant asserts that the teaching in Billoni merely amounts to a hypothesis that the hair growth cycle might be effected by alteration of PPAR-controlled pathways, and views the prior art teaching as an invitation to conduct further research into whether a PPAR- γ activator can effect hair growth. Examiner views that the hypothesis and 'invitation' provides sufficient motivation to make the use of a PPAR- γ activator in regulating hair growth as applicant has done in this case. The prior art may suggest to conduct a further study to investigate the mechanism of the PPAR-controlled pathways in hair growth, and still provide a suggestion and motivation that a PPAR- γ activator

such as 15-deoxy- $\Delta^{12,14}$ -PGD² can be used to alter hair growth. The claimed subject matter is the use of this suggestion. In response to applicant's argument that Billoni provides no expectation of success, examiner respectfully disagrees because the reference in fact suggests that ligands for PPAR- δ and - γ would regulate hair growth: the legal standard for obviousness merely requires reasonable expectation of success, which the Billoni reference provides. Examiner thus views that a prima facie case of obviousness is established in this case.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GINA C. YU whose telephone number is (571)272-8605.

The examiner can normally be reached on Monday through Friday, from 8:00AM until 5:30 PM..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Gina C. Yu/
Primary Examiner, Art Unit 1617